matographic assay cassette, a test sample (i.e., a sample containing an unknown amount of an analyte of interest) may be run in parallel with a calibration standard (i.e., a sample containing a known amount of the analyte of interest). The response to the known amount of the analyte of interest in the calibration standard on the lateral flow immunoassay device may be used to generate a calibration curve that can be used to quantify the amount of the analyte of interest in the test sample.

[0010] The lateral flow chromatographic assay cassette that includes a test strip and a separate calibration strip cassette may include a base, an absorbent test strip for analyzing an analyte of interest in an experimental sample positioned above the base, and an absorbent calibration strip for running at least one calibration standard positioned above the base in proximity to the absorbent test strip. The device further includes a first sample application zone positioned between a distal end and a proximal end the first absorbent strip, and a second sample application zone positioned between a distal end and a proximal end of the second absorbent strip. A volume of a liquid test sample applied to the first sample application zone and a volume of a liquid calibration standard applied or deposited to the second sample application zone each diffuse (i.e., wick) through their respective absorbent strips from the distal end to the proximal end. Accordingly, the analyte of interest, if present in the experimental sample, and the calibration standard interact with at least a first reporter (e.g., an antibody) immobilized on the first and second absorbent strips to yield a detectable signal.

[0011] The testing device includes a testing apparatus that is configured for collecting data from the lateral-flow chromatographic assay cassette. In one embodiment, the testing device includes a testing apparatus that is configured to be physically coupled to a handheld device (e.g., a smartphone). The testing apparatus couples the lateral-flow chromatographic assay cassette to the handheld device in proximity to a light source, the light source being capable of transmitting at least one wavelength of light configured to yield a detectable signal from the reporter(s), and a detector positioned to capture the detectable signal from the reporter(s). In another embodiment, the testing apparatus may be a stand-alone device that includes its own light source, optics, data capture capabilities, and the like. In such an embodiment, the testing apparatus may be configured to collect assay data from an assay cassette and transfer it to a handheld device (e.g., a smartphone) for analysis and reporting.

[0012] In addition, the system described herein may include an interpretive algorithm stored in a computer readable format and electronically coupled to a handheld device, wherein the interpretive algorithm is configured to (i) calculate a calibration curve based on at least one of a the first calibration standard and the second calibration standard or a known amount of an analyte of interest and a blank region and then (ii) convert the detectable signal from the reporter(s) to a numerical value related to the presence or amount of the at least one analyte present in a sample. The interpretive algorithm may be included in an on-board computing system of the handheld device or the interpretive algorithm may be stored remotely in a computer storage medium that is accessible by the handheld device.

[0013] In another embodiment, a method for detecting at least one analyte of interest in a sample is disclosed. The method includes (1) providing a lateral-flow chromatographic assay cassette as described herein above, (2) providing a testing device as described herein above, and (3) applying a liquid sample that includes at least one analyte of interest to the lateral-flow chromatographic assay cassette. The method further includes (4) inserting the lateral-flow chromatographic assay cassette into the testing apparatus, (5) illuminating the lateral-flow chromatographic assay cassette with the light source of the handheld device in order to yield a detectable signal from the reporter(s), and (6) querying the interpretive algorithm for (i) calculating the calibration curve and then (ii) converting the detectable signal from a first reporter to a numerical value related to the presence or amount of the at least one analyte present in a sample.

[0014] These and other objects and features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] To further clarify the above and other advantages and features of the present invention, a more particular description of the invention will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. It is appreciated that these drawings depict only illustrated embodiments of the invention and are therefore not to be considered limiting of its scope. The invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0016] FIG. **1** illustrates a perspective view of a diagnostic test system, according to one embodiment of the present disclosure;

[0017] FIGS. **2**A and **2**B illustrates a lateral flow immunoassay device according to one embodiment of the present invention;

[0018] FIGS. **3**A and **3**B illustrates a lateral flow immunoassay device according to another embodiment of the present invention;

[0019] FIG. **4**A illustrates a plan view of a diagnostic test system that includes a digital camera device and a testing apparatus configured to couple the lateral-flow chromatographic immunoassay cassette to the digital camera device;

[0020] FIG. **4**B illustrates a side view of the diagnostic test system of FIG. **4**A;

[0021] FIG. **5**A illustrates an exploded view of the diagnostic testing system that is illustrated in FIGS. **4**A and **4**B;

[0022] FIG. **5**B illustrates a view of a component of the diagnostic test system shown in FIG. **5**A, wherein the component includes a light sealing feature;

[0023] FIG. **6** illustrates a view of a diagnostic test system that includes an indexing feature for aligning the digital camera device and the testing apparatus;

[0024] FIG. **7**A is a cut-away view of a testing apparatus of a diagnostic test system illustrating a target device configured for normalizing and/or calibrating the light source and the detector of the diagnostic test system;

[0025] FIG. **7**B is a cut-away view of a testing apparatus of a diagnostic test system illustrating a mechanical interlock feature configured to interlock with a corresponding second mechanical interlock feature on a lateral-flow chromatographic assay cassette;

[0026] FIG. **8** illustrates a lateral-flow chromatographic assay cassette packaging system that includes a tracking feature readable by the handheld device;